

### REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Claims 2-8 and 13 were rejected under 35 U.S.C.103(a) as being unpatentable over U.S. Patent No. 6,191,236 to Roby et al. (hereinafter referred to as "Roby '236"). Claims 9-11 and 14 were rejected under 35 U.S.C.103(a) as being unpatentable over Roby '236 in combination with U.S. Patent No. 6,235,869 to Roby et al. (hereinafter referred to as "Roby '869"). These rejections are respectfully traversed.

According to §2142 of the MPEP, the legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. (Emphasis added.)

The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to

support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at 398, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

Further, and in accordance with §706.02(j) of the MPEP, 35 U.S.C. §103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. §103, the examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made (Emphasis added.)

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Turning now to the Examiner's rejections under 35 USC 103, the Examiner states the following:

[T]hat Roby et al [Roby '236] does not explicitly teach the third draw ratio (i.e., in claims 1 and 13, step (e)), which would have been obvious to one of ordinary skill in the art at the time the invention was made in the process of Roby I [Roby '236] principally in order to manufacture a monofilament suture having

desired characteristics and/or properties.” (Emphasis added.) (see page 3, lines 8-13 of the Office Action dated December 4, 2008)

The Examiner states that Roby ‘236 fails to expressly teach the claimed process. Nowhere does the Examiner state that Roby ‘236 impliedly teaches or suggests the claimed process. Rather, the Examiner makes a mere conclusory statement that the claimed process would have been obvious to one skilled in the art.

In view of KSR and the relevant sections of the MPEP, i.e., 2142 and 706.02(j) recited above, the Examiner must provide more than a conclusory statement to satisfy his burden of support of a rejection under 35 USC 103. In other words, the Examiner must provide a convincing line of reasoning as to why the claimed process would be obvious to one skilled in the art. Failure to provide such an explanation means the Examiner has not met his initial burden of factually supporting a *prima facie* conclusion of obviousness. Thus, Applicant is under no obligation to submit evidence of nonobviousness with regards to claims 2-8 and 13 and respectfully requests the withdrawal of the rejection of claims 2-8 and 13 under 35 USC §103 as being unpatentable over Roby ‘236.

Since claims 9-11 and 14 depend from independent claims 1 and 13 and the Examiner asserts the rejection under 35 USC 103 with Roby ‘236 as applied to claims 2-8 and 13, the Examiner has not met his initial burden of factually supporting a *prima facie* conclusion of obviousness for claims 9-11 and 14. Accordingly, Applicant is under no obligation to submit evidence of nonobviousness with regards to claims 9-11 and 14 and respectfully requests the withdrawal of the rejection of claims 9-11 and 14 under 35 USC §103 as being unpatentable over Roby ‘236 as applied to claims 2-8 and 13 and in view of Roby ‘869.

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In view of the foregoing remarks, reconsideration of the application and allowance of claims 2-11, 13 and 14 is earnestly solicited.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to telephone Applicant's undersigned representative at the number indicated above.

Respectfully submitted,



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